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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,589	05/10/2001	Christopher T. Fey	HSA-102XC1	5040

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EXAMINER	
TOMASZEWSKI, MICHAEL	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,589	FEY ET AL.	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *19 October 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Notice To Applicant

1. This communication is in response to the application filed on 10 May 2001. Claims 1-12 are pending. The IDS statement filed on 19 October 2001 has been entered and considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Macri et al. (5,920,871; hereinafter Macri).

(A) As per Claim 1, Macri discloses a method of health data management, comprising the following steps, for each of a plurality of clients:

(a) collecting demographic information from a client, the client having assigned thereto a unique client identifier (Macri: col. 7, line 64-67; col. 8, lines 1-14; Fig. 2B);

(b) conducting a medical screening on the client, wherein said screening comprises at least one genetic test (Macri: col. 3, lines 37-40; col.6, lines 58-62);

(c) storing results from said at least one test in a database (Macri: col. 3, lines 37-40);

(d) analyzing results in conjunction with risk factors associated with the client (Macri: col. 3, lines 58-65);

(e) generating a report for the client according to said analysis (Macri: col. 3, line 62); and

(f) pre-populating an electronic health record for remote access by the client (Macri: col. 6, lines 4-7).

(B) As per Claim 2, Macri discloses the method of Claim 1 further comprising the step of:

combining the results of a plurality clients to provide aggregate information and providing access to said aggregate information (Macri: col. 14, lines 66-67 and col. 15, lines 1-15).

(C) As per Claim 4, Macri discloses the method of Claim 1 wherein the step of analyzing results in conjunction with risk factors comprises, for each of a plurality of risk factors:

(a) assigning unique identifier for said risk factor (Macri: col. 8, lines 1-15) ((Examiner considers the name of a risk factor (e.g., "ethnic group #," "Smoking," etc.) to be a "unique identifier."));

(b) establishing a risk assessment question associated with said risk factor (Macri: col. 9, lines 1-31);

(c) inquiring of the client said risk assessment question, storing response to said risk assessment question (Macri: col. 9, lines 45-56); and

(d) determining positive or negative risk factor based on said response (Macri: col. 9, lines 1-31) (Examiner considers determinations of responses to certain questions as either a positive or negative risk factor to be immediately apparent. For example, responding in the affirmative to the question as to whether the patient has had a previous child with Down Syndrome would be a negative risk factor in that it evidences a higher probability that the patient's future progeny will be afflicted with Down Syndrome because of the mother's genetic predisposition.).

(D) As per Claim 7, Macri discloses the method of Claim 1 wherein the steps are performed for each of a plurality of clients in an organization wherein said organization

has assigned thereto a unique organization identifier and said organization identifier is associated with each client who is a member of the organization (Macri: col. 5, lines 66-67) (Examiner considers a "hospital number" to read on "unique organization identifier.").

(E) As per Claim 8, Macri discloses a computer system for health data management, comprising:

(a) input means for collecting demographic information from a client, the client having assigned thereto a unique client identifier, receiving and storing results in a database from at least one genetic test conducted during a medical screening on the client (Macri: col. 4, lines 24-40; Fig. 1);

(b) processing means for analyzing results in conjunction with risk factors associated with the client and pre-populating an electronic health record for remote access by the client (Macri: col. 7, lines 20-32; Fig. 1); and

(c) output means for generating a report for the client according to said analysis (Macri: col. 7, lines 32-35; Fig. 1).

(F) Claim 9 differs from system claim 1 by reciting "[a] computer readable media containing program instructions for ..." within its preamble. As per these elements, Macri's method and system for medical testing and screening includes computers, data storage devices, communication devices, server systems, network systems and software applications running in tandem with various hardware devices (Macri: col. 7,

lines 20-54; Fig. 1). As such, it is readily apparent that Macri's method and system for medical testing and screening is controlled by a computer program stored upon a computer-readable medium.

The remainder of claim 9 repeats the same limitations of claims 1, and is therefore rejected for the same reasons given for claim 8 above, and incorporated herein.

4. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Joao (6,283,761; hereinafter Joao).

(A) As per Claim 10, Joao discloses a computerized storage and retrieval system for health data management comprising a data storage means for storing data in a relational database wherein the database comprises tables, each table having a domain of at least one attribute in common with at least one other table, said tables comprising:

(a) at least one table for storing demographic information pertaining to a client (Joao: col. 7, lines 49-61);

(b) at least one table for storing information pertaining to a risk assessment (Joao: col. 7, lines 49-61);

(c) at least one table for storing responses to the risk assessment (Joao: col. 7, lines 49-61);

(d) at least one table for storing risk factors for the risk assessment (Joao: col. 7, lines 49-61);

(e) at least one table for storing information pertaining to client screening (Joao: col. 7, lines 49-61);

(f) at least one table for storing common test information for tests that the client takes (Joao: col. 7, lines 49-61); and

(g) at least one table for storing genetic test results for tests that the client takes (Joao: col. 7, lines 49-61).

Examiner also notes that it is well known that relational databases by definition store information in the form of multiple interrelated tables to facilitate quick retrieval of desired data and to leverage the use of relational query languages, such as SQL, to perform structured data queries.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macri as applied to claim 1 above, and further in view of Coli et al. (6,018,713; hereinafter Coli).

(A) As per Claim 3, Macri fails to expressly disclose the method of Claim 1 wherein the step of storing results from said test in a database comprises:

(a) associating a unique identifier for each test taken by the client with said client identifier; and

(b) storing results wherein said results have assigned thereto a unique results identifier, said results identifier associated with said client identifier.

Nevertheless, these features are old and well known in the art, as evidenced by Coli. In particular, Coli discloses the method of Claim 1 wherein the step of storing results from said test in a database comprises:

(a) associating a unique identifier for each test taken by the client with said client identifier (Coli: Fig. 18) (Examiner considers a correlating date and time to be a "unique identifier" for each test and the client's name or account # to be a "client identifier."); and

(b) storing results wherein said results have assigned thereto a unique results identifier, said results identifier associated with said client identifier (Coli:

Fig. 18) (Examiner considers a correlating date and time to be a "unique results identifier" for each test associated with the client's name or account #.).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Coli within the Macri system with the motivation of providing an improved networked computer system for integrated electronic test selection and results reporting (Coli: col. 2, lines 65-67).

Examiner notes also that under the Macri system, the sample number would provide a "unique identifier" for each test, as would the test name or the specimen sample collection date – all of which are included as data entered under the Macri system. Similarly, any of the demographic information (e.g., client/patient name, social security number, etc.) entered under the Macri system would provide a "client identifier."

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macri as applied to claim 1 above, and further in view of Rappaport (US 2002/0007285; hereinafter Rappaport).

(A) As per Claim 5, Macri fails to expressly disclose the method of Claim 1 wherein the report generated for the client according to said analysis comprises:

(a) a screening summary comprising test name, client results, and normal ranges;

(b) a detailed report comprising educational information for each of said tests conducted during client screening;

(c) said educational information comprising test name, client results, normal ranges associated health risks, recommendations, and test protocols; and

(d) a physician's report comprising test name, client results, and normal ranges.

Nevertheless, these features are old and well known in the art, as evidenced by Rappaport. In particular, Rappaport discloses the method of Claim 1 wherein the report generated for the client according to said analysis comprises:

(a) a screening summary comprising test name, client results, and normal ranges (Rappaport: pg. 14, par. [0220]; Fig. 12A-12C);

(b) a detailed report comprising educational information for each of said tests conducted during client screening (Rappaport: pg. 14, par. [0220]; Fig. 12A-12C);

(c) said educational information comprising test name, client results, normal ranges associated health risks, recommendations, and test protocols (Rappaport: pg. 5, par. [0057]; pg. 14, par. [0220]; Fig. 12A-12C); and

(d) a physician's report comprising test name, client results, and normal ranges (Rappaport: pg. 14, par. [0220]; Fig. 12A-12C).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Rappaport within the Macri system with the motivation of efficiently and effectively locating and obtaining relevant, useful, and targeted information concerning the results and data of laboratory tests, procedures, and other medical services (Rappaport: pg. 1, par. [0005]).

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macri as applied to claim 1 above, and further in view of Snowden (US 2002/0026332; hereinafter Snowden).

(A) As per Claim 6, Macri discloses the method of Claim 1 wherein the step of populating an electronic health record for remote access by the client comprises:

(b) automatically storing demographic information collected from said client (Macri: col. 7, lines 64-67); and

(d) allowing client to update file with additional data (Macri: col. 11, line 52);

Macri, however, fails to expressly disclose the method of Claim 1 wherein the step of populating an electronic health record for remote access by the client comprises:

(a) establishing a remotely accessible secure file for said client;

(c) automatically storing test results for said client for each screening; and

(e) allowing client to control access to data by others.

Nevertheless, these features are old and well known in the art, as evidenced by Snowden. In particular, Snowden discloses the method of Claim 1 wherein the step of populating an electronic health record for remote access by the client comprises:

(a) establishing a remotely accessible secure file for said client (Snowden: pg. 3, par. [0079]);

(c) automatically storing test results for said client for each screening (Snowden: pg. 2, par. [0073]); and

(e) allowing client to control access to data by others (Snowden: pg. 3, par. [0079]).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Snowden within the Macri system with the motivation of empowering the patient to take greater personal responsibility for their health and well being and provide the client with full control and ownership of their medical records (Snowden: pg. 2, par. [0073]).

9. Claim 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macri in view of Joao (6,283,761; hereinafter Joao).

(A) As per Claim 11, Macri discloses a computer system for storing and retrieving health data comprising:

(b) means for collecting and storing demographic information from a client in said database, the client having assigned thereto a unique client identifier (Macri: col. 7, lines 23-45);

(c) means for conducting a medical screening on the client, wherein said screening comprises at least one genetic test (Macri: col. 3, lines 55-61);

(d) means for storing results from said at least one test in said database (Macri: col. 7, lines 39-41);

(e) means for analyzing results in conjunction with risk factors associated with the client (Macri: col. 3, lines 58-61); and

(f) means for generating a report for the client according to said analysis on the basis of the data stored in the relational database (Macri: col. 3, lines 66-67).

Macri, however, fails to expressly disclose a computer system for storing and retrieving health data comprising:

(a) a relational database for storing data comprising a plurality of interrelated tables wherein each table comprises an attribute having a common domain with an attribute of at least one other table in the database.

Nevertheless, this feature is old and well known in the art, as evidenced by Joao. In particular, Joao discloses a computer system for storing and retrieving health data comprising:

(a) a relational database for storing data comprising a plurality of interrelated tables wherein each table comprises an attribute having a common domain with an attribute of at least one other table in the database (Joao: col. 7, lines 49-61).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Joao within the Macri system with the motivation of facilitating the creation and management of a comprehensive healthcare processing system which can manage patient and client records (Joao: col. 2, lines 38-41).

(B) Claim 12 substantially repeats the same limitations of Claim 10, and is therefore rejected for the same reasons given for that claim.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches methods for diagnosing, preventing, and treating developmental disorders due to a combination of genetic and environmental factors (6,912,492); genetic profiling and banking system and method (6,640,211); computer architecture and process of patient generation, evolution, and simulation for computer based testing system (6,246,975); a process for requesting biological experiments and for the delivery of experimental information (US 2004/0142371); and a system and method for providing a server-based wireless communication of medical test requests and results (US 2002/0026331).

The cited but not applied prior art also includes non-patent literature articles by Business Editors ("LabDat Announces Patient Access To Clinical Laboratory Reports" Dec. 20, 1999. Business Wire. pg. 1.); Steve Connor ("NHS Urged To Plan For New Genetic Tests" Dec. 14, 1998. The Independent. pg. 7.); and Timothy Caulfield ("Gene Testing In The Biotech Century: Are Physicians Ready?" Nov. 2, 1999. Canadian Medical Association. Journal. Vol. 161, Iss. 9. pg. 1122.).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT MT 8.29.05

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